PhotoMedex

XTRAC® ULTRA

Excimer Laser Phototherapy System

AL8000 SERVICE MANUAL

PhotoMedex

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PhotoMedex shall not be liable for errors contained herein or for incidental or consequential damage in connection with furnishing, performance, or use of this material.

Use of this manual is not intended for individuals who have not received appropriate training.

Individuals who have not received formal training by an authorized PhotoMedex trainer cannot service the XTRAC Phototherapy System. Attempts to service the XTRAC system without authorized training may cause serious injury to the service technician and/or operator and will also void the warranty.

This manual provides no information on the clinical use of the laser.

REVISION HISTORY

Pages/Sections	Revision	ECO	Date
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Page 36	B	2548	03/09/05
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Pages 30-32	G	2896	5/22/07

Table of Contents

REVISION HISTORY 3
1.0 CAUTION 6
2.0 GENERAL SAFETY FOR OPERATING PERSONNEL AND PATIENTS 6
2.1 User Responsibilities for Appropriate Operation 7
3.0 WARNINGS, LABELING AND SYMBOLS 7
3.1 Warnings 7
3.2 Labeling 8
4.0 DEVICE DESCRIPTION 12
4.1 Manufacturer and EU Representative 12
4.2 Standards 12
4.3 XTRAC XeCl Excimer Laser Phototherapy System Specifications 12
4.4 XTRAC Equipment Classification per UL 60601-1 13
5.0 INDICATIONS 13
6.0 TRANSPORT AND STORAGE 13
Before Shipping the XTRAC system: 14
6.2 Transport and storage conditions are defined as follows: 14
7.0 UNPACKING THE SYSTEM AND PERFORMING SYSTEM SET-UP 14
8.0 INSTALLING THE FOOTSWITCH 14
9.0 USING THE SYSTEM ROOM-DOOR INTERLOCK (OPTIONAL) 15
10.0 ADJUSTING SYSTEM VOLTAGE AND FREQUENCY 15
11.0 POWER-ON WARM-UP MODE 15
12.0 EMERGENCY LASER STOP 16
13.0 OPERATING THE SYSTEM IN THE SERVICE MODE 16
13.1 Accessing Service Mode in the XTRAC 16
14.0 GAS BOTTLE INSTALLATION 17
14.1 Neon Purge Set-up 17
14.2 Connecting Neon Purge & Attaching or Exchanging XeCl Cylinder 17
14.3 Removing the Neon Purge 19
15.0 ALIGNMENT AND LIQUID LIGHTGUIDE INSTALLATION 20
15.1 Introduction 20
15.2 Alignment and Alignment Check Procedures 22
15.3 PIN Diode Calibration 23
15.4 Install the Lightguide 24
16.0 GAS BOTTLE CAPACITY MAINTENANCE 25

17.0 WINDOW CHANGE PROCEDURE 26

17.1 NEON PURGE SET-UP 26
17.2 CONNECTING NEON PURGE 26
17.3 REPLACING THE CHAMBER WINDOW ASSEMBLIES 26
17.4 REMOVING THE NEON PURGE 28
17.5 RE-GASSING AND RE-ALIGNMENT OF THE LASER CHAMBER 28

18.0 WINDOW ROTATION PROCEDURE 28

18.1 ROTATING THE CHAMBER WINDOW ASSEMBLIES 28
18.2 VERIFY LASER CHAMBER ALIGNMENT 29

19.0 XTRAC TROUBLESHOOTING AND EVENT CODE GUIDE 29

19.1 TROUBLESHOOTING GUIDE 29
19.2 EVENT CODE AND GAS HISTORY GUIDES 30

20.0 MAINTENANCE 33

20.1 SCHEDULE OF PREVENTIVE MAINTENANCE 33
20.2 ENERGY DETECTOR CALIBRATION VALIDATION (PER 15-90014-01) 34
20.3 CLEANING THE XTRAC SYSTEM 35

21.0 REFERENCES 35

21.1 INTELLECTUAL PROPERTY 35
21.2 REFERENCE DOCUMENTATION 35
21.3 DISPOSAL 36

22.0 REPLACEMENT PARTS 36

APPENDIX A - DEFINITION OF TERMS 44

APPENDIX B - MSDS FOR XECL 45

APPENDIX C - ADDITIONAL DOCUMENTS 46

1.0 CAUTION

This Service Manual is intended to be used only by persons who have been trained to service this product. Procedures and instructions are to be followed as indicated. All cautions, precautions and warnings should be thoroughly understood prior to unpacking, assembling and operating the XTRAC system.

CAUTION: AVOID DIRECT OR SECONDARY LASER RADIATION. The XTRAC phototherapy system is a laser-based device. When interlocks have been placed in the "service mode" there is the potential for laser energy to be present. Use precaution when operating the system in this mode. Always wear appropriate safety glasses, which are designed to block 308nm UVB wavelength energy.

CAUTION: Potentially lethal voltages are present within the XTRAC system. Always use caution when performing any service or maintenance to the system.

CAUTION: This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. If it causes unwanted interference the operator should consult the laser service representative. Changes or modification not expressly approved by PhotoMedex could void the user's authority to operate the equipment.

CAUTION: Do not operate the laser in the presence of flammable anesthetics or oxidizing gases such as nitrous oxide (N_2O) and oxygen.

2.0 GENERAL SAFETY FOR OPERATING PERSONNEL AND PATIENTS

- Laser equipment not in use should be protected against unqualified use, for example by removal of the key from the key switch.
- The invisible ultraviolet laser radiation emitted from the XTRAC system output laser aperture can cause eye and/or skin injury from either direct radiation. Only a trained user should operate the laser.
- The use of controls or adjustments, or performance of procedures, other than those specified in this labeling may result in hazardous radiation exposure.
- Users and support staff must wear eye protection during laser operation. The recommended safety eyewear should have an optical density (OD) of 2 at a wavelength of 308 nm.
- Do not look into the end of the handpiece when the laser is firing.
- Do not point the handpiece at operating room personnel when the laser is firing.

2.1 User Responsibilities for Appropriate Operation

It is the responsibility of the health care professional who is using the laser to be aware of requirements for safe use. It is strongly recommended that a hospital Laser Safety Officer be responsible for the overall control of the laser and safety training. **Note**: Laser equipment not in use should be protected against unqualified use (e.g. by removal of the key from the key switch). The responsibilities of a Laser Safety Officer are described in American National Standard for Safe Use of Lasers in Health Care Facilities ANSI Z136.3 2000.

The user is responsible for reading and following the XTRAC Operations Manual and for exercising all safety precautions recommended in the Operations Manual and product labeling including the use of eye protection at all times that the system is activated.

3.0 WARNINGS, LABELING and SYMBOLS

3.1 Warnings

WARNING: The invisible ultraviolet laser radiation emitted from the XTRAC system output port aperture can cause severe eye and/or skin injury from radiation. Only a trained user should operate the laser.

WARNING: The repair technician must exercise extreme care when operating the laser; safety glasses must be worn and skin exposure must be avoided.

WARNING: The use of controls or adjustments, or performance of procedures, other than those specified in this labeling may result in hazardous radiation exposure.

WARNING: At all times during the installation or operation of the laser, avoid possible exposure to laser radiation.

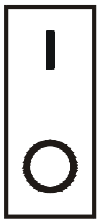
WARNING: Users and support staff must wear eye protection during laser operation. The recommended optical density for Safety eyewear is an optical density (OD) of 2 at a wavelength of 308 nm. The patient's eyes should be protected with a covering of wet gauze.

WARNING: High voltage circuits are contained within the XTRAC system enclosure.

3.2 Labeling

Throughout the system you will find labels applied to various areas, which are designed to warn or caution of certain hazards or other precautionary information. This section will provide an outline of each symbol and it's meaning. The current revisions of each label are filed with Document Control.

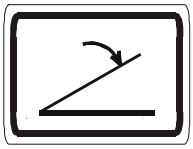
Description
Circuit Breaker



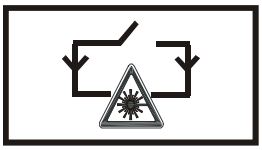
On

Off

Description
Foot-switch



Description
Remote Interlock



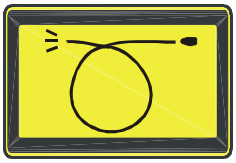
Description
Defeatable Interlock

CAUTION - VISIBLE AND INVISIBLE CLASS 4 LASER
RADIATION WHEN OPEN AND INTERLOCKS DEFEATED
AVOID EYE OR SKIN EXPOSURE TO
DIRECT OR SCATTERED RADIATION

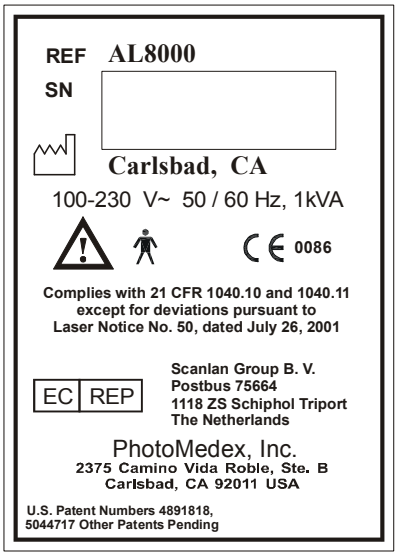
Description
Label, Calibration Port

CALIBRATION
PORT

Description
Optical Fiber

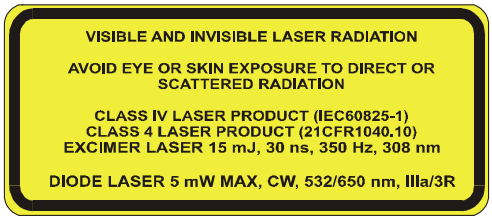


Description
Label, Nameplate, AL8000

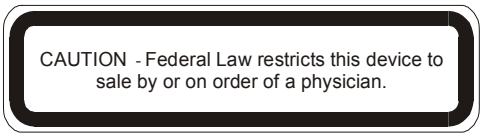


Description
Laser Warning, Danger

Description
Laser Warning Explanation Class IV

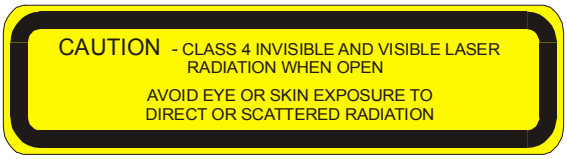

VISIBLE AND INVISIBLE LASER RADIATION
AVOID EYE OR SKIN EXPOSURE TO DIRECT OR
SCATTERED RADIATION
CLASS IV LASER PRODUCT (IEC60825-1)
CLASS 4 LASER PRODUCT (21CFR1040.10)
EXCIMER LASER 15 mJ, 30 ns, 350 Hz, 308 nm
DIODE LASER 5 mW MAX, CW, 532/650 nm, IIIa/3R

Description
Label, Physician Use Only (FDA Reqd.)



Description
Attention – Yellow or White

Description
Caution, Invisible


CAUTION - CLASS 4 INVISIBLE AND VISIBLE LASER RADIATION WHEN OPEN
AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION

3.3 Symbols

Symbol	Description	Symbol	Description
	Batch Code	REF	Model Number
	B Equipment	**LASER APERTURE**	Laser Aperture Location
	Date and location of Manufacture		On Main Off
	Emergency Laser Stop	CE 0086	Product complies with Directive 93/42/EEC for medical devices
EC REP	European Representative		Read Instructions For Use
	Fiberoptic Applicator		Ready Key
	Footswitch		Remote Interlock
	Fragile	SN	Serial Number
	Keep Dry		Temperature Limitation
	Laser Aperture (Symbol)		Laser Emission
	On Part of System		MED Ready Mode
	Off		

4.0 DEVICE DESCRIPTION

4.1 Manufacturer and EU Representative

Manufacturer:	**EU Representative:**
PhotoMedex, Inc.	Scanlan Group B.V.
2375 Camino Vida Roble, Suite B	Postbus 75664
Carlsbad, CA 92011	1118 ZS Schiphol Triport
	The Netherlands

4.2 Standards

The XTRAC (model AL8000) Excimer laser phototherapy system is a class IV Laser product, which complies with (US Code of Federal Regulations) 21 CFR 1040.10 and 1040.11 & IEC 60825-1.

The XTRAC system has tested in compliance with the safety laser requirements and electromagnetic compatibility per the following international standards:

EMC STANDARDS	**SAFETY STANDARDS**
EN 60601-1-2	EN 60601-1
EN 55011, Class A, Group 1	EN 60601-2-22
	EN 60825
	21 CFR 1002
	UL 60601-1
	IEC 60601-2-22

4.3 XTRAC XeCl Excimer Laser Phototherapy System Specifications

The XTRAC system is an Excimer laser designed for use in phototherapy treatment.

The XTRAC has been designed around a pulsed, 308 nanometer XeCl excimer laser which provides:

Wavelength	308 nanometers
Pulse Repetition Rate	Up to 250Hz
Pulse Width (FWHM)	30-nanosecond nominal
Beam Diameter	0.75 in square (2cm X 2cm)
Operating Energy	2-3.8 mJ/cm² (nominal per pulse)
Electrical	100/230 VAC, 50/60 Hz, 1 kVA, universal
Weight	220 lb / 100 kg (approximate)
Gas System	Self Contained Supply (approx 20 refills)
Dimensions	46 cm x 99 cm x 86 cm (W x L x H) 18 inches x 39 inches x 34 inches
Excimer Laser Product Classification	Class IV per 21 CFR 1040.10 / IEC 60825-1
Diode Laser Product Classification	Class IIIa/3R per 21 CFR 1040.1/ IEC 60825-1
Nominal Ocular Hazard Distance	20 cm from the handpiece tip
Maximum Laser Energy	15mJ
Beam Divergence	750 mRad

4.4 XTRAC Equipment Classification per UL 60601-1

Type of protection against electric shock-	Class I equipment
Degree of protection against electric shock-	Type B equipment
Degree of protection against harmful ingress of water-	Ordinary equipment without ingress protection
Degree of safety in the presence of flammable anesthetic mixture with air or oxygen or nitrous oxide-	Equipment is not suitable to use in the presence of flammable anesthetic mixture with air or oxygen or nitrous oxide
Mode of Operation-	Continuous operation

Liquid Lightguide and Handpiece: **MODEL H7-4.0**

LLG Material	Proprietary liquid filled housing
Length	2.0 meters
Diameter	3.0 mm nominal
Input	Custom connector (user replaceable)
Output	Custom connector
HP Material	Aluminum–housing
Projected Field	≈ 0.75 in square (4.0 cm^2)

Handpiece Tip & Ink pad Kit : **MODEL K7-4.0**

Supplied non-sterile, with reusable Handpiece Marking Tip

5.0 INDICATIONS

Phototherapy with the XTRAC UVB Excimer Laser Phototherapy system is indicated for patients with Psoriasis, Vitiligo, Atopic Dermatitis or Leukoderma.

6.0 TRANSPORT AND STORAGE

Preparing the XTRAC system is to be performed only by PhotoMedex authorized service representatives.

If the system has been exposed to extreme temperatures, the unit must be returned to room temperature (15-25ºC) before operating. This is best accomplished by allowing the system to be left in a room temperature environment overnight before operation.

Caution: **DO NOT** attempt to lift the unit with the handles.

NEVER attempt to pull the unit by the power cord or the handpiece.

- Enter "CYLINDER" routine in service mode and vent the chamber to 17 psig.
- Remove the gas cylinder** by performing the following steps from section 14.2:
  - Perform Steps 2 through 6, then 15 through 18
  - Next, immediately install the aluminum shipping plug with KEL-F washer into the flex line to the XeCl gas bottle and tighten. Failure to do so will contaminate the laser and void the warranty.
  - Finally, perform steps 20 and 23, and exit from the cylinder screen and shut the laser off.
  - Remove the Neon purge per section 14.3, then remove gas cylinder.
- Remove the foot switch assembly.
- Remove the lightguide and handpiece assembly.

** It is ***illegal*** to transport a pressurized cylinder, which is not properly prepared with an appropriate safety cap!

6.2 Transport and storage conditions are defined as follows:

Temperature:	-40º C - +70º C
Humidity:	90% RH max. non-condensing
Atmospheric Pressure:	500 hPa – 1060 hPa

7.0 UNPACKING THE SYSTEM AND PERFORMING SYSTEM SET-UP

If the XTRAC system has been subjected to extreme temperatures, follow the directions in the section titled "*Transport and Storage"* prior to applying power to the system.

Remove the carton straps then open carton top and lift the ramp out at the front end of machine. Next remove the carton baseboards 4 sides by removing the screws then lift the carton over the top of the machine. Remove the accessory boxes under the machine and platform and unbolt the machine from the platform. Place ramp at the front of the crate and guide the machine down the ramp off the crate platform. Save the shipping container in the case that the system may be moved to another location.

Inspect the condition of the unit. If there is evidence of damage due to shipment, contact your PhotoMedex representative for instructions.

8.0 INSTALLING THE FOOTSWITCH

Locate the foot switch that was shipped with the unit (part number 01-08230-01).

NOTE: The XTRAC ULTRA footswitch is NOT compatible with any other XTRAC model (XTRAC, XTRAC XL, or XTRAC XL Plus).

(The foot-switch is located inside the XTRAC system restrained in the location where gas bottle is to be placed.)

- Insert the foot switch in the receptacle on the Rear Interface panel located on the rear of the unit. The footswitch label identifies the correct receptacle.
- Verify that the action of the foot switch is smooth and positive.

9.0 USING THE SYSTEM ROOM-DOOR INTERLOCK (OPTIONAL)

The safety/remote interlock is a black-colored plug (P/N 03-08420-01) that is plugged into the main power panel. You may hardwire this interlock in series to a switch on the entry door of the room where you use the XTRAC using the Interlock wiring assembly (P/N 01-08234-01). Authorized individuals, such as an electrician, can only perform this. When anyone opens the room's entry door the interlock is activated, preventing the laser from firing until the door is closed. Once the interlock circuit is normalized, and the RESET key is pressed, the laser will function normally. The current/voltage running through the interlock is 0.005 amps and 0.7 volts.

Neither the plug nor the interlock wiring can be used with any other equipment other than the XTRAC ULTRA.

If you remove the safety interlock at any time after you turn on the laser, lasing will stop. A matching plug with the pins internally connected is provided for service personnel to test the XTRAC system.

If the safety interlock has an open circuit (the room entry door is open), laser functions are inhibited. Once the interlock circuit is normalized (the room entry door closes), and you press the Reset Key, the laser will function normally.

10.0 ADJUSTING SYSTEM VOLTAGE AND FREQUENCY

The AL8000 power supply accepts supply voltage of 100 thru 230 Volts AC and frequencies of 50 or 60Hz. No manual adjustments are required for voltages and frequencies within these ranges.

The XTRAC system is supplied (normally) with a hospital grade AC male connector, within the United States. For International systems, the power cord has flying leads. You will need to install a plug that is appropriate for your installation.

CAUTION: Failure to install the proper AC connector for the XTRAC system may result in damage.

11.0 POWER-ON WARM-UP MODE

Power On Mode enables the XTRAC system to perform power-on self-tests prior to its clinical use. It also provides access to the system SET UP options and the treatment billing information screen. Power On is activated when you turn on the main power switch. The warm-up period enables the Thyratron tube within the XTRAC system to warm up to an adequate temperature prior to firing the laser. This period lasts five minutes.

1. The footswitch is inactive in this operating mode.
2. The software version is displayed on the top line of the display panel.
3. The setup mode and system information modes are available during system warm-up.

12.0 EMERGENCY LASER STOP

On the top of the control panel is a red Emergency Laser Stop button. The button will remain down when pressed. When the laser is fired with the button depressed a system error will be displayed along with the message "RELEASE EMERGENCY STOP BUTTON". This is normal, and should not be interpreted as a system fault. If the button is pressed while the laser is firing, the laser will stop firing. While this button is down, the laser will not fire. Note that this button is easily accessed, as is necessary in case a quick stop is required. Note also that there are arrows on the button to indicate a rotation direction. To release the button, turn in the direction indicated by the arrows.

13.0 OPERATING THE SYSTEM IN THE SERVICE MODE

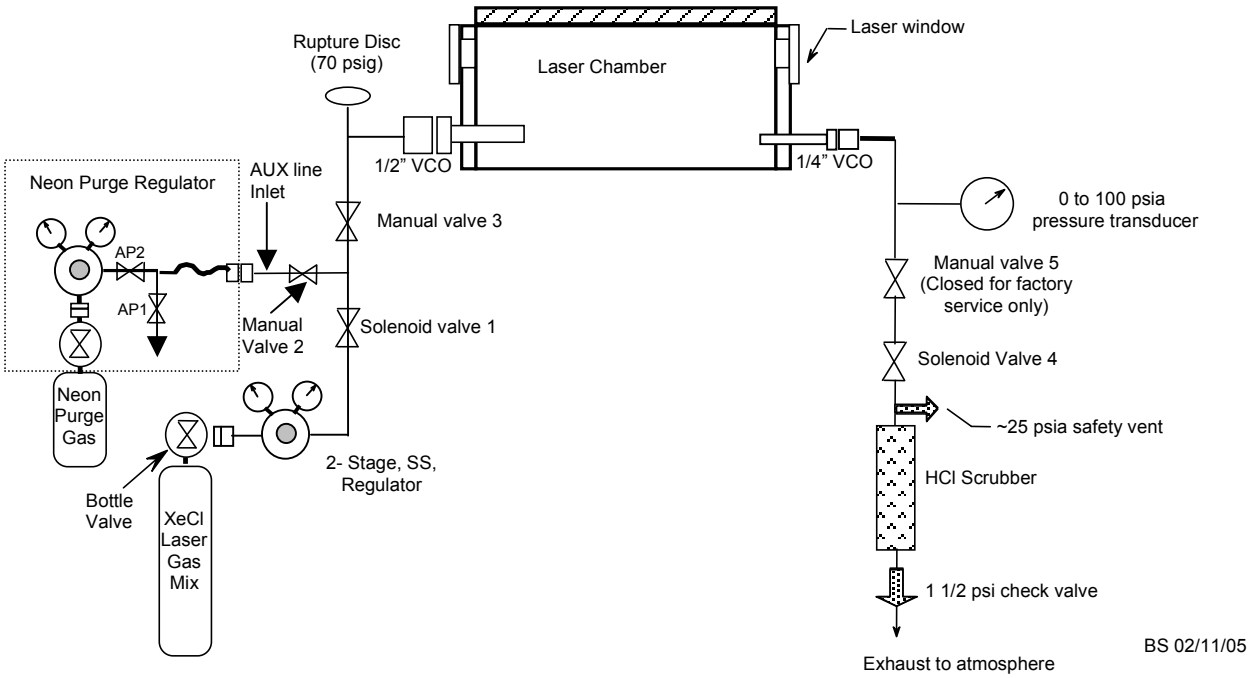
The XTRAC system can be operated in a "Service Mode" by using the service key switch located on the Rear Interface panel located on the rear of the unit. By using this feature, you can perform special functions that will allow you to isolate and verify specific functions of the system.

13.1 Accessing Service Mode in the XTRAC

1. Turn system power off.
2. Insert service key, part of the XTRAC ULTRA Specialty Tool Kit, into the switch, located on the rear of the unit, and turn on to set the laser to Service Mode
3. Turn system on. The laser will now allow the technician to manually manipulate the high voltage, repetition rate and gas system settings.

14.0 GAS BOTTLE INSTALLATION

PhotoMedex Gas System Connections
(Using Laser Gas Purge)



14.1 Neon Purge Set-up

1. With both **AP 1 & 2** valves *closed*, and the Neon purge line VCO cap in place, *open* the Neon cylinder main valve and set the pressure to ~5-10 psig.
2. Crack *open* valve **AP 1 & 2** and purge the line with Neon for ~5 seconds, then *close* **AP1**.
3. Remove the VCO cap on the Neon purge line, and continue to slowly vent Neon gas through **AP2** and the Neon purge line for ~5 seconds.
4. With **AP2** still *open*, replace the VCO cap on the purge line until ready to use

14.2 Connecting Neon Purge & Attaching or Exchanging XeCl Cylinder

1. Enter "CYLINDER" routine in the laser Service Mode (solenoid valve 1 (FILL) should be *closed*).
2. If the laser system has a XeCl laser gas cylinder attached, *close* the XeCl main cylinder valve now.
3. Make sure the laser manual **valve 2** is *closed*, then *close* manual **valve 3**.
4. Carefully remove the laser AUX line VCO cap and the VCO cap on the Neon purge line (Neon gas will begin to flow since AP2 is open). Clean the mating surfaces with an alcohol wipe, and connect the Neon purge line to the laser AUX line inlet.

5. *Open* **AP1** and vent Neon gas for ~5 seconds, then *close* **AP 1 & 2**.
6. *Open* the laser manual **valve 2**.

IF NO XECL LASER GAS CYLINDER IS ATTACHED, CONTINUE WITH STEP 7.

IF THE LASER SYSTEM HAS A XECL LASER GAS CYLINDER ATTACHED THAT NEEDS TO BE EXCHANGED, PROCEED TO STEP 15.

Note: The laser should have 18 psia in the chamber prior to performing this procedure.

No XeCl Cylinder Attached

7. Open manual **valve 3** and **AP 1** for 3 seconds.
8. Close manual **valve 3** and **AP 1**.
9. *Open* **AP2** to provide a Neon gas purge flow.
10. Open solenoid **valve 1 (FILL)** from the control panel.
11. Remove the threaded metal cap-plug from the XeCl regulator pigtail. (Neon gas should be flowing from the disconnected tube! If this is not occurring, *stop* the procedure immediately and identify why Neon is not flowing. Neon purge gas must be flowing while the regulator pigtail is disconnected to prevent system contamination.)

    Note: Cycle the XeCl regulator handle CW and CCW one turn to facilitate neon gas flow through it. This may need to be done more than one time.
12. With the Neon gas flowing, connect a full laser gas cylinder to the XeCl flex tube (wiping both mating surfaces with Alcohol wipes and using a new gasket).
    NOTE: New gasket must be tightened to approximately 70 in-lbs. If nut holding gasket is loosened for any reason, the gasket must be replaced or the gas bottle WILL leak.
13. *Close* **AP2**.
14. Turn the XeCl regulator pressure adjustment knob fully CCW, slowly *open* the XeCl main cylinder valve, and then adjust the output pressure to 36-40 psig. **However, under any circumstances, never exceed the red marking on the gauge (40psig).** When this step is complete, go to **Step 22**.

XeCl Cylinder Attached

15. Open solenoid **valve 1 (FILL)** using the control panel.
16. Check to make sure the XeCl main cylinder valve is *closed*, and then slowly *open* **AP1** to vent any residual laser gas in the XeCl gas regulator. *Close* **AP1**.
17. *Open* **AP2** to pressurize the XeCl regulator with Neon gas (pressure ~5-10 psig).

18. Carefully disconnect the high-pressure regulator pigtail from the XeCl gas cylinder. (Neon gas should be flowing from the disconnected line! If this is not occurring, *stop* the procedure immediately and identify why Neon is not flowing. Neon purge gas must be flowing while the flex tube is disconnected to prevent system contamination.)
    NOTE: Cycle the XeCl regulator handle CW and CCW one turn to facilitate neon gas flow through it. This may need to be done more than one time.
19. Exchange the used XeCl gas cylinder for a full one, and tighten the flex tube0 connection using a new gasket.
    NOTE: New gasket must be tightened to approximately 70 in-lbs. If nut holding gasket is loosened for any reason, the gasket must be replaced or the gas bottle WILL leak
20. *Close* **AP2**.
21. *Open* the XeCl main cylinder valve and make sure the pressure is set to 36-40 psig. However, under any circumstances, never exceed the red marking on the gauge (40psig).
22. Carefully crack *open* **AP1** and vent laser gas for ~5 seconds, then *close* **AP 1** & manual **valve 2**.
23. *Close* solenoid **valve 1 (FILL)** from the laser control panel.
24. *Open* manual **valve 3**.
25. Enter the value of the XeCl cylinder pressure in the laser control panel screen. This screen should automatically display the approximate number of laser fills available.
26. Exit Gas Service screen and press the Yes button to refill the laser chamber. Return service key switch to the OFF position.

14.3 Removing the Neon Purge

1. *Open* **AP2** and then **AP1** to purge the line with Neon gas for ~5 seconds, then *close* **AP1**.
2. Disconnect the purge line from the AUX inlet connection and while continuing to purge the line, seal the purge line and the AUX inlet using the VCO caps.
3. *Close* the Neon cylinder main valve and valve **AP2**.

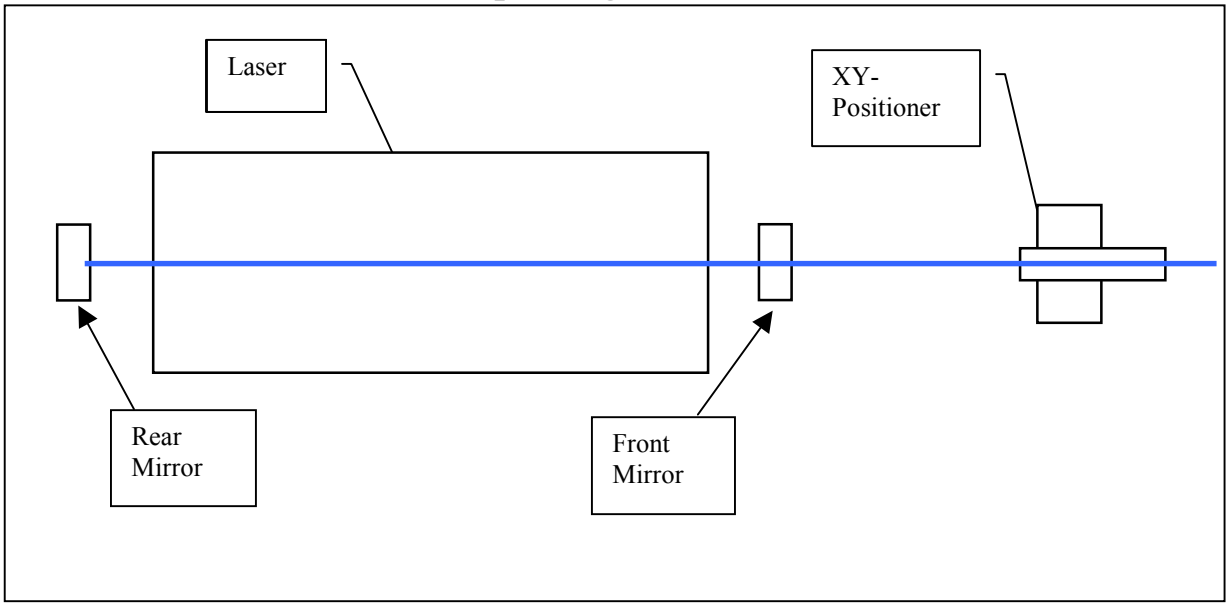
15.0 ALIGNMENT AND LIQUID LIGHTGUIDE INSTALLATION

15.1 Introduction

The alignment of the XTRAC ULTRA laser system presents two independent challenges to the technician. The alignment process therefore, must be viewed as, and performed in two separate steps.

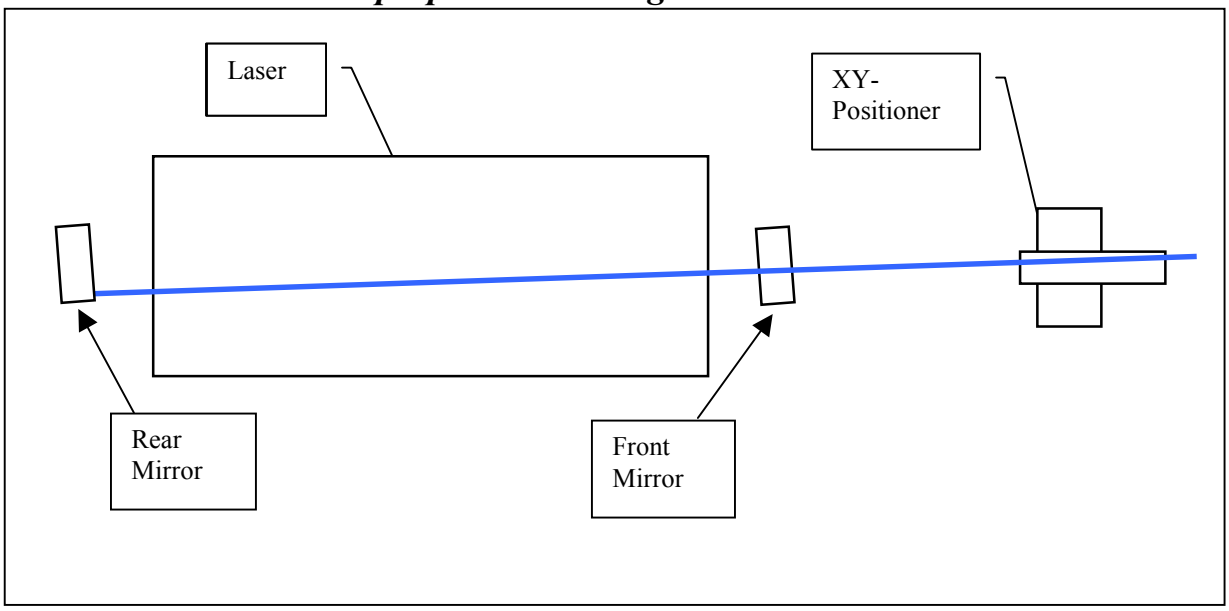
1. The first challenge is achieving proper alignment of the laser cavity. Because the laser mirrors can be set parallel, but also at substantial angles that will all give nearly maximum energy, there needs to be a way to define the optimal alignment axis.
2. The second challenge in the alignment process is the coupling of laser light into the fiber delivery system. Proper alignment into the fiber is critically important to fiber lifetime. The beam should be input directly and precisely perpendicular into the face of the Liquid Light Guide. The beam should also be centered precisely into the 3mm light guide core and there should be no laser light hitting the outer portion of the core. The adjustment process should also be tolerant of minor misalignment of the optical hardware that is inherent in the XTRAC ULTRA laser system.

Proper Alignment



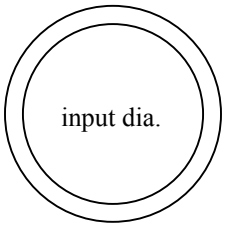
In the above example the laser mirrors are parallel with each other as well as being perpendicular to the laser discharge. This alignment will yield the optimal beam shape and energy.

Improper Mirror Alignment

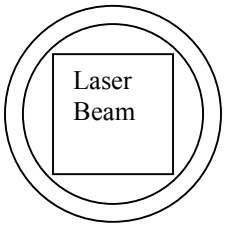


In the above example the laser mirrors are parallel but are *NOT* perpendicular to the laser discharge. This alignment will yield less than optimal energy and beam shape while aiming the beam away from the center of the fiber.

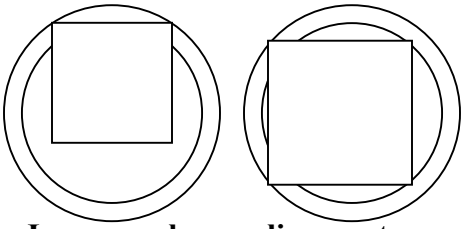
The second challenge in the alignment process is the coupling of laser light into the lightguide delivery system. The beam should be input directly and precisely perpendicular into the face of the lightguide. The beam should also be centered precisely into the lightguide face. The adjustment process should also be tolerant of minor misalignment of the optical hardware that is inherent in the XTRAC laser system.



Lightguide end view



Proper beam alignment



Improper beam alignment

15.2 Alignment and Alignment Check Procedures

1. Laser Mirror Alignment Check
    a. Open top skin and remove left skin as viewed from front of unit.
    b. Insert Alignment chuck into LLG port.
    c. Tape a piece of white paper to top skin interior directly in front of laser outlet.
    d. Install Laser Alignment Pin-Holes on front and rear laser mirrors.
    e. Operate laser at 50 Hz and 7 kV.
    f. Check alignment:
        i. Alignment is OK if a donut is centered in the larger, faint circle of light.
        ii. If the donut is visible but not centered then loosen clamps and iteratively adjust the laser mirrors until centered. Retighten clamps after centering and recheck alignment.
        iii. If the donut is not visible then proceed with full alignment.
2. Laser Mirror Alignment:
    a. Place unit in Service Mode and set Rep-rate to 50Hz and Charge Voltage to 7.0 kV unless otherwise noted.
    b. Rough alignment:
        i. Open top skin and remove left skin as viewed from front of unit.
        ii. Insert Alignment chuck into LLG port.
        iii. Tape a piece of white paper to top skin interior directly in front of laser outlet.
        iv. Run laser and adjust laser mirrors to maximize square-ness and brightness of beam.
    c. Moderate alignment:
        i. Install one (1) Laser Alignment Pin-Hole on rear of laser chamber.
        ii. Align vertical mirror axes iteratively until spots line up along horizontal axis.
        iii. Align horizontal mirror axes iteratively until spots overlap.
    d. Fine alignment:
        i. Install second Laser Alignment Pin-hole on front of laser chamber: output beam shape on white paper is a small bright donut within a larger faint circle.
        ii. Repeat iterative alignment on the horizontal and vertical axes until the donut is centered in the larger, faint circle of light.
    e. Re-tighten the clamps around each of the four alignment screws and ensure that the alignment did not change.
3. XY-Positioner Alignment Check
    a. Open top skin and remove left skin as viewed from front of unit.
    b. Tape a piece of white paper to top skin interior directly in front of laser outlet.

c. Place alignment chuck insert into alignment chuck. **(NOTE: side with smaller hole is inserted first)**, then return chuck to XY-Positioner
d. Operate laser at 50 Hz and 7 kV.
e. Alignment is OK if the beam is rectangular with no clipping of the corners. If there is clipping then proceed with full alignment.

4. XY-Positioner Alignment:
   a. Remove strain relief mounting plate.
   b. Place alignment chuck insert into alignment chuck. **(NOTE: side with smaller hole is inserted first)**, then return chuck to XY-Positioner
   c. Loosen (but do not remove) the four screws holding XY- Positioner to front optical mount plate.
   d. Run laser observing the beam on the white paper. Using a screwdriver, adjust the X and Y-axes on the stage until no circular aperturing of the rectangular beam exists.
   e. Tighten the four screws securing the XY-Positioner. Run laser to insure there is still no circular aperturing.
   f. Install external detector holder onto alignment chuck and attach energy detector.
   g. Run laser for about one minute and record "Apertured" pulse energy.
   h. Remove alignment chuck insert from alignment chuck and replace alignment chuck.
   i. Run laser for about one minute and record "Initial" laser energy.
   j. Calculate "minimum acceptable" energy by multiplying above "Initial" energy by 0.97 and record "minimum acceptable" energy.
   k. If "Apertured" energy is less than minimum acceptable then repeat steps (b) through (k), otherwise procedure is complete.
   l. Remove alignment tools and re-bolt strain relief mounting plate such that strain relief and XY-Positioner are concentric: use alignment chuck as a guide.

5. **Always perform PIN diode calibration after laser mirror or XY-positioner adjustments.**

15.3 PIN Diode Calibration

1. Place unit in Service Mode.
2. Insert alignment chuck into XY-positioner and attach external energy detector holder and system energy detector.
3. Ensure that interlocks will not prevent shutter from opening.
4. Press the **CALIB** touch key then the **DIODE** key.
5. Press the footswitch then the **START** key. Keep footswitch depressed until machine stop firing. PIN Diode is now tuned.
6. Verify PIN Diode Calibration.
   a. Fire laser and adjust input kV to achieve 10, 15, and 20 mJ (±2mJ).
   b. Verify efficiency (EFF) is 100 ± 3% and record value. If efficiency is out of spec, repeat PIN diode calibration. If it continues to be out of spec contact PhotoMedex to discuss possible resolution.

15.4 Install the Lightguide

1. Remove the Laser Handpiece / Delivery Cable from its packaging. Inspect for any damage. If damage is noted, contact PhotoMedex Customer Service immediately. NEVER use a Handpiece /Delivery Cable you may suspect has been damaged.
2. If supplied, remove the protective caps from the Delivery Cable ends. **NOTE: *NEVER*** hold the assembly by the fiber when removing the protective caps, always hold the handpiece or input end bezel while removing the caps.
3. Place the Laser Handpiece / Delivery Cable into the mating connection, carefully inserting the input end as far as it will go into its locating mount until it "clicks" into place. ***Do not*** use any tools to complete this step.

NOTE: The "click" noise made during insertion indicated that the fiber detection switch has been activated. There are two small switches used for this purpose. If you do not hear this noise, or suspect that the switches are not being activated, you must adjust the position of the switches in order to ensure activation. The switches are active when the end portion of the barrel assembly on the fiber cable depresses the curved portion of the switch assembly. **It is extremely important that this adjustment be made correctly, as improper adjustment will prevent the system from operating correctly.**

16.0 GAS BOTTLE CAPACITY MAINTENANCE

Note: The system must be in Service Mode for this procedure.

During routine maintenance of the XTRAC laser system it will be necessary to verify the accuracy of the "FILLS" remaining counter. Check the pressure of the gas cylinder as read on the high-pressure side of the gas regulator and compare it to the displayed pressure reading on the gas screen. Adjust the displayed pressure reading up or down as needed to achieve an accurate reading.

The laser will perform automatic gas exchanges every 5 million pulses or 4 weeks, whichever comes first. The laser operator cannot initiate gas exchanges at any time.

The system will count down as gas exchanges are performed giving a warning at < 600 psi remaining ("Refill supply low, X fills remaining, Contact Service Soon") and an Event Code 14 at 200 psi remaining, which will disable the laser. This gives the system approximately 4 fills between the first low gas warning and the critical Event Code 14.

1. Enter Service Mode.
2. Press the "CYLINDER" then "DONE" buttons to access the gas management screen.
3. Record the displayed and actual values.
4. Enter the value of the XeCl cylinder pressure in the laser control panel screen. This screen should automatically display the approximate number of laser fills available.
5. Press the ENTER key to accept the new values and exit.

If the value between the pressure in the cylinder and the displayed pressure is more than 80 psi, then the "TOP OFFS" value should be checked in the gas management screen. To access the "TOP OFFS" value, perform the following.

1. Enter Service Mode.
2. Press the CYLINDER button to access the gas management screen.
3. The TOP OFF information will be visible in the middle of the screen.

If the laser shows more than 15 TOP OFFS per month on average then a gas leak from the chamber or plumbing may be suspected.

Most systems will exhibit some degree of thermal expansion and contraction of laser gas in the chamber. This expansion and contraction is the reason that most lasers will have some small value of TOP OFFS displayed on the screen. The TOP OFFS value should be reset after any work is performed to the pressure barriers on the chamber such as a window exchange or a pressure transducer replacement.

17.0 WINDOW CHANGE PROCEDURE

This window change procedure uses the neon purge gas and regulator assembly. If you DO NOT have a bottle of neon purge gas or the regulator assembly, then DO NOT attempt to change the windows! The laser will be contaminated and the warranty of the laser will be voided! See Section 14 for valve diagram.

17.1 Neon Purge Set-Up

1. With both **AP 1&2** valves *closed*, and the Neon purge line VCO cap in place, *open* the Neon cylinder main valve and set the pressure to between 5 ±2 psig.
2. Crack *open* valve **AP 1&2** and purge the line with Neon for 5 seconds, then *close* **AP1.**
3. Remove the VCO cap on the Neon purge line, and continue to slowly vent Neon gas through **AP2** and the Neon purge line for 5 seconds.
4. With **AP2** still *open*, replace the VCO cap on the purge line until ready to use.

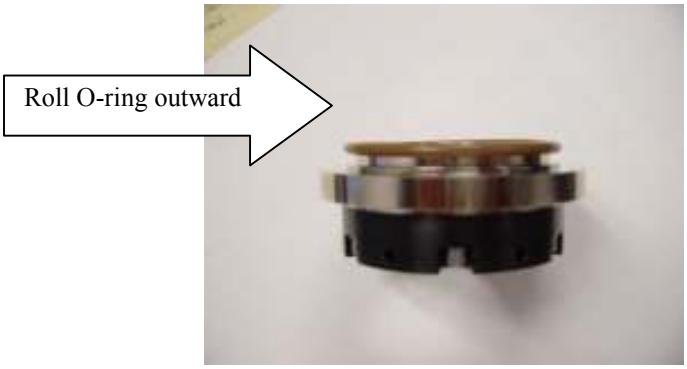
17.2 Connecting Neon Purge

1. Enter WINDOW routine in the laser Service Mode**.**
2. Make sure the laser manual **valve 2** is *closed*, and then *close* manual **valve 3.**
3. Carefully remove the laser AUX line VCO cap and the VCO cap on the Neon purge line (Neon gas will begin to flow since AP2 is open from step I-3. above). Clean the mating surfaces with an alcohol wipe, and connect the Neon purge line to the laser AUX line inlet.
4. Open **AP1** and vent Neon gas for 5 seconds, then close **AP 1&2.**
5. Now, open the laser manual **valve 2.**
6. Using the laser control panel, open solenoid **valve 1 (FILL)** and carefully crack *open* **AP1** and vent laser gas for 5 seconds, then *close* **AP1.**
7. Close solenoid **valve 1 (FILL)** from the laser control panel.
8. Open solenoid **valve 4 (VENT)** from the laser control panel and vent the laser chamber to 17 psia, then close solenoid **valve 4 (VENT)**.
9. Open manual **valve 3** and **AP2** to introduce neon into the chamber for positive pressure when the chamber windows are removed.

17.3 Replacing the Chamber Window Assemblies

1. Lock front wheels of laser.
2. Remove Rear Interface Panel (two bolts) and drape over the side.
3. Remove the rear optical plate to gain access to the windows.
4. Verify cleanliness of the replacement window assemblies and locate them where they can be easily accessed.

5. Remove the rear window assembly by removing the six (6) outer most screws on the window flange. A small amount of laser gas will escape the chamber and the neon gas should begin to immediately flow. If this is not occurring, *stop* the procedure, immediately re-attach the window, and identify why Neon is not flowing. Neon purge gas must be flowing while the chamber is open to atmosphere to prevent system contamination.
6. If any white powder, dirt or other contamination is observed carefully clean the window flange area on the laser chamber with an alcohol wipe or a cotton swab with methanol.
7. Roll the O-ring to the outer edge of the window flange.



8. Place the replacement window assembly in front of the laser window flange, allowing neon purge gas to flush the air from the window assembly.
9. To prevent O-ring damage, tilt the window so that the bottom edge of the window is first inserted into the end flange. Press downward on the window assembly to compress the bottom edge of the O-ring and then press the window into place.

10. Be sure to leave the white registration line in the uppermost position. The window flange is a metal-to-metal fit; so **don't** over tighten these screws.
11. Snug down all six hex-head screws used to attach the window assembly.
12. Rotate the window one full turn, this will help to identify if the O-ring was damaged when the chamber is pressurized.

13. Align position #1 with the white registration line using a spanner wrench.
14. Replace the rear optical plate assembly using the spacing tool to maintain proper optical plate gapping. Then replace the Rear Interface Panel.
15. Repeat steps 4-13 for the front window assembly. (Note: To gain access to the front window remove the two screws holding the shutter assembly and move shutter assembly out of the way. Next loosen, but do not remove, the four middle optics plate clamps. Slide/walk the middle optics plate toward the front optics plate. **Note: cover the laser mirror on the middle optics plate to prevent damage or being touched during the window change.**
16. Slide/walk the middle optics plate back toward the laser. Use the two delrin spacers to precisely set the gap between the middle and front optics plates then tighten the clamps on the middle plate. Replace the shutter assembly.
17. Close manual **valve 3**.

17.4 Removing the Neon Purge

1. Close manual **valve 2** and verify that **AP2** is still open**.**
2. Disconnect the purge line from the AUX inlet connection and while continuing to purge the line, seal the purge line and the AUX inlet using the VCO caps.
3. *Close* the Neon cylinder main valve and valve **AP2.**

17.5 Re-gassing and re-alignment of the laser chamber

1. Open manual **valve 3**.
2. From the laser control panel, press the DONE button and then the YES button to perform a gas exchange.
3. Verify that the XeCl regulator is set between 36-40 psig. **(**Do not exceed the red marking on the gauge (36 psig) under any circumstances.)
4. Re-align the laser per Section 15.
5. Return the laser to standard operating mode.
6. The procedure is now complete.

Carefully package and return the used window assemblies to PhotoMedex for re-work. Ensure that the windows are returned under an RMA number.

18.0 WINDOW ROTATION PROCEDURE

Windows should only be rotated when the laser is no longer able to produce 20mJ at 8.0kV after alignment and gas exchange.

18.1 Rotating the Chamber Window Assemblies

1. Insert the spanner wrench into the window assembly.

2. Rotate the assembly to line the next highest number on the window with the registration mark. **Note**: This type of rotating window has six positions. If the window is already on position number six (6) then the window assembly must be replaced. See Section 17 for replacement procedure.

18.2 Verify laser chamber alignment

Always check the alignment of the laser cavity and turning mirrors after rotation of the windows! Re-align the laser per Section 15.

19.0 XTRAC Troubleshooting and Event Code Guide

Use of the following tables will be useful in helping the technician isolate and resolve system malfunctions. If resolution cannot be obtained after exhausting these guides, please contact PhotoMedex to discuss possible resolution.

19.1 Troubleshooting Guide

Common system malfunctions with solutions.

SYMPTOM	POSSIBLE CAUSES	SUGGESTED ACTION
Laser Will Not Start	1. XTRAC ULTRA Circuit breaker not set to on position. 2. Power cable not plugged into system or wall outlet. 3. Supply (room) breaker is turned "off"	1. Turn XTRAC ULTRA breaker to on position. 2. Check power cable connections 3. Check room breaker.
Laser Will Not Fire	1. Thyratron not up to temperature. 2. Footswitch not connected. 3. Internal system problems.	1. Let laser warm-up for an additional 15 minutes and try again. 2. Connect footswitch. 3. Contact PhotoMedex.
No Response to Buttons or Foot switch	1. Interlock circuit was opened.	1. Close interlock circuit breaker located at the back of the laser, then press "Reset" button OR if the interlock circuit has been connected to a door in the room, close the door and press "Reset".
No Display, No Sound From Unit	1. Key Switch was turned off. 2. XTRAC Ultra breaker switch is off. 3. Supply (room) breaker is turned "off".	1. Turn Key Switch to ON position. 2. Turn breaker switch on, then restart unit. 3. Check room breaker.

19.2 EVENT CODE AND GAS HISTORY Guides

Event codes are displayed on the XTRAC front panel and are used to report functional abnormalities that are monitored by the MCU (Master Control Unit). A comprehensive listing of all event codes is provided for reference.

EVENT CODE GUIDE – Software Version 4.10.1

EVENT NUMBER	SYSTEM EVENTS	BRIEF DESCRIPTION / ACTION
0 – 9	UNDEFINED	undefined error - implies software problem CALL CARLSBAD, REPLACE MCU / DETECTOR
10	CRITICAL_VALUE_ERROR	NOV RAM value error during MemCheck REPLACE MCU / DETECTOR
11	A2D_ERROR	A/D wasn't ready when it should have been REPLACE MCU / DETECTOR
12	MEMORY_INIT_FAILED	after making RAM copy of NOVRAM variables, MemCheck failed REPLACE MCU / DETECTOR
13	PRESSURE_TRANSDUCER_BAD	reading from pressure transducer is below possible reading CHECK PRESSURE TRANSDUCER/CABLE, CHECK MCU / DETECTOR
14	OUT_OF_GAS	no more refills remaining as calculated from bottle pressure REPLACE GAS BOTTLE
15	RAM_ERROR_DETECTED	failed RAM test at power on REPLACE CPU CHIP OR MCU / DETECTOR
16	NOVRAM_RETENTION_FAILED	failed NOVRAM test at power on REPLACE MCU / DETECTOR
17	CHAMBER_PRESSURE_LOW	failed minimum pressure test at power on, implies leak in chamber SEARCH FOR LEAK
18	ROM_ERROR_DETECTED	failed ROM test at power on REPLACE EPROMS OR MCU / DETECTOR
19	UNINITIALIZED_CODE	software not initialized properly (billing-vs-non-billing) REPLACE MCU / DETECTOR
20	TOO_LONG_TO_VENT	time exceeded during venting of chamber while exchanging gas CHECK GAS SCRUBBER, VALVES/SOLENOIDS
21	TOO_LONG_TO_PURGE	time exceeded during purging ... CHECK REGULATOR, VALVES/SOLENOIDS
22	TOO_LONG_TO_FILL	time exceeded during filling ... CHECK REGULATOR, VALVES/SOLENOIDS
23	**NOT USED**	N/A
24	PFN_FAILURE	pfn didn't discharge CHECK PFN / THYRATRON, CHECK MCU, OR CHECK WIRE W14
25	HVPS_FAILURE	power supply didn't charge CHECK HVPS
37	NB_SERVICE_MANDATORY	service mandatory due to pulse count since last service visit (NB only) ENTER SERVICE MODE TO CLEAR
38	WDT_EXPIRED	watch dog timer timed out REPLACE MCU / DETECTOR
39	WRONG_VERSION	Version verification failed... REPLACE EPROMS WITH CORRECT VERSION
40	**NOT USED**	N/A

EVENT NUMBER	SERVICE REQUIRED EVENTS	BRIEF DESCRIPTION / ACTION
41	UNABLE_2_ACHIEVE_TWICE	even after a gas exchange, the system couldn't achieve min energy CHECK ALIGNMENT, ROTATE / REPLACE WINDOWS, CHECK POWER SUPPLY OR PFN/THYRATRON
42 – 50	** NOT USED **	N/A
WARNING NUMBER	RECORDED WARNINGS	BRIEF DESCRIPTION / ACTION
51	HANDPIECE_NOT_IN_CALPORT	system couldn't verify handpiece in cal port during calibration CHECK CALPORT MICROSWITCHES
52	PIN_DIODE_EXCEEDED_MAX	energy at PFD exceeds maximum allowed to protect the fiber CHECK SHUTTER, CHECK HVPS BIAS
53	SENSOR_RATIO_LESS_THAN_40_PCNT	ratio of energy from end of fiber and PFD is lower than allowed CHECK ALIGNMENT, CHECK LLG, CHECK OPTICS PANEL BOARD
54	UNABLE_2_ACHIEVE_MIN_ENERGY	low energy from laser SEE EVENTS 80 TO 87 THIS EVENT CODE IS NEITHER SEEN NOR RECORDED
55	FOOTSWITCH_INACTIVE	can't verify footswitch active during cal CHECK FOOTSWITCH AND WIRING
56	KEYSWITCH_INACTIVE	keyswitch turned off (relay stuck?) CHECK RELAY BOARD
57	** NOT USED **	N/A
58	SHUTTER_FAILURE	shutter wouldn't open or close as required CHECK ALL INTERLOCKS, CHECK SHUTTER/CABLES
59	NB_SERVICE_NEEDED	service needed due to pulse count since last service visit (NB only) ENTER SERVICE MODE TO CLEAR
60	HVPS_DAC_MALFUNCTION	HV power supply DAC failed during SelfTest REPLACE MCU / DETECTOR
WARNING NUMBER	UNRECORDED WARNINGS	BRIEF DESCRIPTION / ACTION
61	FIBER_NOT_CONNECTED	system tried to move shutter, and found fiber not connected... CHECK FIBER MICROSWITCHES
62	LID_OPENED	service lid is opened CHECK POSITION OF LID SWITCH AND CONNECTIONS
63	ESTOP_PRESSED	the ESTOP button is pressed
64	PROCESS_ABORTED	user cancelled an operation in progress
65	ACCOUNT_DEPLETED	no more codes in the treatment bank...
66	INVALID_CODE_ENTRY	invalid number entered in billing
67	**NOT USED**	N/A
68	REMOTE_INTERLOCK_BROKEN	remote interlock was de-activated during calibration or treatment
69	**NOT USED**	N/A
70	SCREEN_CALIBRATION_FAILED	touch panel calibration routine failed PUSH RECAL SCREEN BUTTON AND RETRY
71	SYSTEM_NOT_WARMED_UP	PIN1_DIODE_VALUE_ZERO but system hasn't been active for at least 5 min. CHECK DIP SWITCHES: ALL MUST BE OFF

WARNING NUMBER	UNRECORDED WARNINGS	BRIEF DESCRIPTION / ACTION
72	SYSTEM_NOT_TUNED_YET	division by zero in cal routine - diode hasn't been tuned yet TUNE PIN DIODE
73	FOOTSWITCH_ACTIVE	footswitch active when it shouldn't be
74	CAL_PORT_ACTIVE	cal port active when it shouldn't be
75-79	** NOT USED **	N/A
WARNING NUMBER	RECORDED WARNINGS	BRIEF DESCRIPTION / ACTION
80	LOW_ENERGY_0	Low energy – Auto Gas Pressure Adjustment to Follow: Gas Code 105
81	LOW_ENERGY_1	
82	LOW_ENERGY_2	
83	LOW_ENERGY_3	
84	LOW_ENERGY_4	
85	LOW_ENERGY_5	
86	LOW_ENERGY_6	
87	LOW_ENERGY_7	

GAS HISTORY GUIDE

GAS CODE	PROCESS	BRIEF DESCRIPTION
101	CHAMBER_TOP_OFF	topping off chamber pressure (too low)
102	CHAMBER_VENTING	venting off chamber pressure (too high)
103	PULSE_COUNT_EXCEEDED	too many pulses since last exchange
104	TIME_ELAPSED	too much time since last exchange
105	CAL_FAILURE	gas exchange after event #80-87- calibration failed
106	EXCHANGE_RESTART	gas exchange restarting / never finished last time powered up
107	MANUAL	gas exchange started from service mode manually
108	PRESSURE_BUMP	gas pressure increased from 35 to 45psia

20.0 MAINTENANCE

All service and preventive maintenance is to be performed by qualified PhotoMedex representatives. A schedule of required maintenance is provided in this section. It is required that the areas listed be serviced on the schedule as indicated in order to maintain proper system performance and operation. Failure to perform required maintenance will result in the inability of the XTRAC to perform as designed. A copy of all preventative maintenance as performed must be sent to PhotoMedex, Carlsbad CA as evidence of completion.

20.1 Schedule of Preventive Maintenance

See following table for list of required preventive maintenance.

Schedule of Required Preventative Maintenance:

FUNCTION:	1 year	2 years	3 years	As Reqd.	Each Service Visit
Scrubber		R			I
Gas Bottle				R	I
Regulator					I
System Plumbing					I
Shutter Assembly	I				I
Panel Light Bulbs				R	I
System Fan Filters	R				C
System Hardware					I
Handpiece & Light Guide				R	I
Energy Detector	R*				I

R = Replace I = Inspect Clean = Clean

*** If the calibration date on the energy detector has expired, the energy detector must be replaced and/or re-verified against a traceable standard – see Section 20.2.**

20.2 Energy Detector Calibration Validation (per 15-90014-01)

1. Inspect Nova II Exposure Meter, adapter and Standard Energy Detector (standard) for physical damage. If damaged the complete unit must be re-calibrated at PhotoMedex, Carlsbad before using.
2. Verify that the software version on the AL8000 is 3.00 or greater. If not, upgrade the unit to latest software revision.
3. Place the AL8000 laser system in service mode and warm up the machine for at least five minutes.
4. Place the liquid light guide into the machine, then, after pressing the CALIBRATE button and the STANDARD button, insert the LLG hand piece into the Cal Port and calibrate. After calibration, the system shows the calibration summary screen. Hit EXIT once to continue.
5. Insert the hand piece into the Standard Energy Detector and press the footswitch to deliver a 1000 mJ dose. Observe the actual dose displayed on the exposure meter and record on Form AF-0205. Press the display screen once to reset.
6. Repeat Step 5 for three more doses and record on AF-0205.
7. Insert hand piece into the cal port and press the footswitch to deliver a 1000 mJ dose to the System Energy Detector. Observe the actual dose on the system display and record the value on Form AF-0205. Press the display screen once to reset.
8. Repeat Step 7 for three more doses and record on AF-0205.
9. Touch the screen abort button to return to stand by mode.
10. Average the four doses into the Standard Energy Detector and the four doses into the Cal Port (System Energy Detector) and determine the error of the AL8000 Energy Detector relative to the Standard Energy Detector and record on Form AF-0205.
11. If the error is less than or equal to ± 6% the System detector has passed calibration validation.
    a. Fill out a Calibration Label (P/N 12-95272-01) completely. Enter date of calibration, calibration due date (18 months after Cal date), S/N of Reference Energy Detector (attached to Nova II), and the Service Engineers initials.
    b. Attach securely to the back of the AL8000 System Energy Detector Head.
    c. Return completed Form AF-0205 to PhotoMedex, Carlsbad, QA-Department ASAP.
12. If the error is greater than ± 6% re-test per Steps 3 to 10 and record data on AF-0205.
13. If the error is greater than ± 6% for a second time the system detector has failed calibration validation.
    a. Remove the System Energy Detector and MCU and return, along with Form AF-0205, to PhotoMedex, Carlsbad, QA-Department ASAP.
    b. Install a new MCU and System Energy Detector and repeat Steps 3 to 10.
    c. Complete paperwork and return to QA department at PhotoMedex in Carlsbad, CA

20.3 Cleaning the XTRAC System

The exterior of the laser unit may be cleaned using water with a *mild* detergent. Never use solvents or other harsh chemicals to clean the exterior portion of the system. Never attempt to clean the output lens of the handpiece assembly.

21.0 REFERENCES

21.1 Intellectual Property

PhotoMedex, Inc. is the owner of United States patent number 4891818 and 5044717 that covers the XTRAC laser system. Additional patents pending.

21.2 Reference Documentation

- Operating instructions for the XTRAC system can be found in the Operations Manuals # 12-95305-01 and 12-95350-01.
- Premarket Notification Approvals (510k) number that FDA has granted for the AL8000 is K0419343. Summaries of the application and approval order are available from FDA.

NOTE: SOP's (or Standard Operating Procedures), which comprise the PhotoMedex Quality System, are required to be followed by all PhotoMedex employees.

- SOP-026; Complaint Handling Procedure
- SOP-019; Servicing
- AF-0037; Complaint Form
- AF-0192; Field Service Report
- AF-0135; Return Material Authorization Tag
- 15-90014-01; Energy Detector Calibration Validation Procedure
- AF-0205; XTRAC ULTRA Energy Detector Calibration Validation Report
- 12-95272-01; Calibration Label

21.3 Disposal

The laser consists of the following items, which may be pertinent to disposal in accordance with the laws and ordinances governing the site of disposal:

1. The laser consists of an aluminum frame, steel panels, a nickel-plated aluminum chamber and miscellaneous plastic parts.
2. The laser system contains printed circuit boards with standard commercial components.
3. The halogen scrubber contains inert molecular sieve and indicating soda lime (calcium oxide and sodium hydroxide). Soda lime reacts exothermally with water to form an alkaline solution so caution should be taken when mixing with water. A solution of the soda lime may be neutralized with common baking soda or a mild acid such as vinegar by appropriately trained personnel.

22.0 Replacement Parts

Listed below is a list of replacement parts for the XTRAC Excimer laser phototherapy system.

Assy/Part #	Description
01-05280-01	Gas Scrubber
01-07795-02	Rotating Window Assembly, 6-position
01-08040-99	Control Panel Assembly
01-08097-01	Handpiece Tip and Ink Pad Assembly
01-08100-01	Cleaning Kit for LLG
01-08104-01	Liquid Light Guide Delivery System Kit (includes tips and cleaning kit)
01-08208-99	PFN Top Assembly
01-08222-xx	Software PROMS A and B Assembly Version of software needs to be provided for ordering
01-08225-xx	Software PROMS A and B Assembly Version of software needs to be provided for ordering
01-08223-99 05-70233-06	MCU Assembly Pyroelectric Energy Detector
01-08224-99	Optics Panel Board
01-08229-99	Relay Panel Board
01-08230-01	Footswitch Assembly
01-08231-99	Photodiode Assembly
03-08420-01	Remote Interlock, Plug
04-07802-01	Micro Switch – X Y Positioner, Fiber Switch
05-70098-26	FUSE 1.25A/250V 5X20MM FAST ACT, Optics Board
05-70098-27	FUSE 6.3A/250V 5X20MM FAST ACT, Relay Board
05-70098-28	FUSE 1.6A/500V Slo-Blo, Inside PFN

Assy/Part #	Description
05-70098-29	FUSE 0.6A/500V Slo-Blo, Inside PFN
05-70204-24	Power Supply, High Voltage, Output 120VAC-10KVDC-24VDC
05-70204-24	Power Supply, High Voltage, Output 120VAC-10KVDC-24VDC
05-70225-16	Switch, Modification, Cal.Port
05-70225-18	Switch, Panel Mount, DPST
05-70236-07	Led, High Intensity, Yellow
05-70236-08	Led, High Intensity, Green
05-70399-04	Relay, Panel Mount Solid State, Din Rail
06-80022-17	Air Filter, 5.5x5.5
06-80023-12	Fan Tangential
06-80023-13	Fan, Galaxy, DC, Bottom of System
06-80023-14	Fan, Sprint, 24V, Front of PFN
06-80023-15	Fan, Muffin XL 24V, Rear of PFN
06-80064-23	Regulator, VCO Inlet, SS
06-80071-14	Washer, KEL-F
06-80071-13	Gas Bottle
06-80275-12	Key #311
06-80275-26	Tubular Key, Top Panel Key
06-80280-09 06-80310-02	Polyethylene Dust Cover Velcro Fastener

Appendix A - Definition of Terms

◊ **Excimer Laser** - A pulsed, 308-nanometer XeCl laser that, in the XTRAC system, provides the Phototherapy action spectrum required to provide dermatological treatment.

◊ **Fiberoptic/ Liquid Light Guide** - In the XTRAC system this term is used to describe the probe/cable that carries laser energy to the patient.

◊ **HVPS** - High Voltage Power Supply

◊ **kV** - Kilovolts

◊ **mJ** - Millijoules is used to express laser energy.

◊ **PPS** - Pulses Per Second. In the XTRAC system this refers to the number of LASER firing pulses per second.

◊ **System Events** - Events that necessitate a system power down or diagnostic procedure to allow continued operation assuming the condition has been corrected. Often, this is to assure starting the system from a known state.

◊ **Thyratron Tube** - A component within the XTRAC system that is used to switch on and off the current from the high voltage capacitor bank enabling the activation of the laser.

◊ **VF** - Vacuum fluorescent

APPENDIX B - MSDS for XeCl

MATERIAL SAFETY DATA SHEET — ISSUE AND REVISIONS March 16, 2001

Chemical Name & Synonyms	Hydrogen Chloride/Xenon/ Neon gas mixture	Formula	n/a
Chemical Family	Inorganic Acid-Rare Gas	Manufacturer	Nova Gas Technologies, Inc.
Proper Shipping Name	Compressed gas, nos,	Manufacturer's Address	913 Commerce Circle Charleston, SC 29406
DOT Hazard Class	2.2	Manufacturer's Phone Number	843-747-0956
DOT Hazard Label	Nonflammable Gas	Chemtrec Phone Number	800-424-9300
UN Number	UN1956		

II. INGREDIENTS

Principal Hazardous Components & Percent	Hydrogen Chloride/Xenon/ Neon gas mixture	Threshold Limit Value (units)	5 ppm* *5 ppm is the TLV for Hydrogen Chloride; Neon and Xenon has none but may act as an asphyxiant

III. PHYSICAL DATA

Boiling Point	n/a	Specific Gravity (H20=1)	n/a
Vapor Pressure (mm Hg.)	n/a	Percent Volatile by Volume (%)	100.0%
Vapor Density (Air=1)	n/a	Evaporation Rate (___=1)	n/a
Solubility in Water	Slight		
Appearance & Odor	Pungent, toxic, corrosive gas with sharp pungent odor.		

IV. FIRE & EXPLOSION HAZARD DATA

Flash Point (Test Method)	n/a	Auto Ignition Temperature	n/a
Flammable Limits	n/a	LEL UEL	n/a n/a
Extinguishing Media	n/a		
Special Fire Fighting Procedures	When fighting fires in which Hydrogen Chloride is involved, firefighters must wear protective suits and self-contained breathing apparatus.		
Unusual Fire & Explosion Hazards	Cylinders exposed to fire may rupture with explosive force. Spray water on them to keep them cool.		

V. HEALTH HAZARD DATA

Threshold Limit Value	See section II*	Symptoms of Exposure	Irritation of the eyes, skin, mucous membranes and breathing passages. Causes choking, coughing and burns.
OSHA Threshold Limit Value	5 ppm (ceiling)*		
ACGIH Threshold Limit Value	5 ppm (ceiling)*		
Carcinogen			
NTP Program	not listed		
IARC Program	not listed		

APPENDIX B – (continued)

VHEALTH HAZARD DATA	
Medical Conditions Aggravated By Exposure	Nose & throat irritation
Primary Route(s) of Entry	Inhalation and contact with body tissues
Emergency First Aid	Inhalation: Move victim to fresh air. If breathing has stopped, give artificial respiration & if necessary, oxygen. Get medical aid. Eye & Skin irritation: Flush area with large amounts of water for minimum of 15 minutes. Get medical aid.

VI REACTIVITY DATA			
Stability			
Unstable		Conditions to Avoid	Keep away from excessive heat
Stable	X		
Incompatability			
Hazardous		Materials to Avoid	Fluorine, Ammonia, Ozone, Unsaturated Organic compounds and bases.
Polymerization			
May Occur			
Will Not Occur	X	Conditions to Avoid	Keep away from excessive heat.
Hazardous Decomposition Products	Hydrogen and Chlorine are formed slowly at room temperature		

VII ENVIRONMENTAL PROTECTION PROCEDURES	
Spill Response	Evacuate the area. If possible shut off the flow of gas. Personnel with acid suits and self-contained breathing apparatus may attempt to stop the leak. Ventilate the area.
Waste Disposal Method	Replace the outlet plug in the cylinder valve. Replace the cylinder cap. If no leaks are detected, return the cylinder to your supplier.

VIII SPECIAL PROTECTION INFORMATION			
Eye Protection	Safety goggles	Skin Protection	Leather work gloves
Respiratory Protection	If needed, self contained breathing apparatus	Ventilation Recommended	Mechanical
Other Protection	Safety shoes		

IX SPECIAL PRECAUTIONS	
Hygienic Practices in Handling & Storage	Use only in well ventilated areas. Store away from excessive heat
Precautions for Repair & Maintenance of Contaminated Equipment	Make sure that all residual vapors are removed prior to beginning R&M
Other Precautions	Move cylinders with a hand truck

APPENDIX C - ADDITIONAL DOCUMENTS

00-08000-01	AL8000 Domestic Assembly Tree
00-08030-01	Optics Wiring Schematic
00-08205-01	Power Supply Wiring Schematic
00-08218-01	Wiring Harness Assembly Schematic
15-08005-03	Wiring Inspection Guide
AF-0192	AL8000 Field Service Report
SP-006	AL8000 Installation Procedure
AF-0205	XTRAC ULTRA Energy Detector Calibration Validation Report
12-95272-01	Calibration Label

Replace this page with current revision of documents listed in Appendix C.